IN THE UNITED STATES DISTRICT
COURT WESTERN DIVISION FOR THE
NORTHERN DISTRICT OF OHIO

Ohio Stands Up! and Kristen Beckman, et al. , Plaintiff Attorneys: Thomas Renz (Bar ID 98645) 1907 W State St. #162 Fremont, OH 43420 & Robert Gargasz (Bar ID 7136) 1670 Cooper Foster Park Rd. Lorain, OH 44053 & N. Ana Garner (NM Bar ID#921) 1000 Cordova Pl., #644 Santa Fe, NM 87505 (pending *pro hac vice* approval)	)	CASE NO. 3:20 CV 2814
-vs-	)	JUDGE: James R. Knepp II
The United States Department of Health and Human Services (DHHS), Center for Disease Control (CDC), DHHS Secretary Norris Cochran, CDC Director Rochelle Walensky,,National Center for Health Statistics (NCHS), NCHS Director Brian C. Moyer, Office of Management and Budget Director Shalanda Young, John and/or Jane Does 1-20,	)	AMENDED COMPLAINT

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COMPLAINT: FEDERAL QUESTION

Plaintiffs by their attorneys files this Complaint against Defendants and allege as follows:

Nature of the Action

1. This is an action concerning violations of the Paperwork Reduction Act ("PRA"), the Information Quality Act ("IQA"), the Administrative Procedures Act ("APA"), and the Implied Constitutional Duty of Honesty and Fair Dealing.

2. Plaintiffs are seeking declaratory and injunctive relief regarding these violations, or, in the alternative, a writ of mandamus against the Office of Management and Budget ("OMB"). A formal prayer for relief may be found at the end of this Complaint.

Parties

A. Plaintiffs and Injury

The Plaintiffs in this action are:

3. **Ohio Stands Up!** Ohio Stands Up! is an Ohio organization of Ohio citizens whose mission is to challenge the state of emergency Ohio ("Emergency"), challenge the various emergency mandates, orders and restrictions issued by Ohio Governor Mike DeWine and his Cabinet that are predicated on the existence of the Emergency ("Emergency Mandates"), uphold Constitutional rights, and educate about the realities of COVID-19.

4. The Emergency Mandates are driven and purportedly justified by the COVID-19 "case" and "death" counts tabulated and published by the Defendants. The "case" and "death" counts, in turn, are based on substantive rules for death certificate reporting and polymerase chain reaction ("PCR) testing that violate the "integrity" and "utility" clauses of the PRA, the IQA, and

the rulemaking procedures of the APA. Ohio induces compliance with the Emergency Mandates by instilling fear in the public using aggressive reporting of the "case" and "death" counts. Thus, the illegal substantive rulemaking has aggrieved, adversely affected the interests of, and injured Ohio Stands Up! and its members in numerous ways. Their injuries include:

- Ohio Stands Up! has been wrongly accused of reporting false data, censored on social media for reporting information on COVID-19 that differed from the misleading data presented by officials, and defamed in the press for similar reasons. Its First Amendment rights to free speech and association have been violated,
- Members of Ohio Stands Up! have suffered economic loss from business closures and restrictions, discrimination under the Americans with Disabilities Act, violations of their Constitutional right to freedom of movement, violations of their First Amendment rights to free exercise of religion and free speech.

5. **Kristen Beckman** – Oregon, OH. Kristen Beckman is a private citizen whose rights have been repeatedly trampled by the Emergency Mandates. Kristen has both a medical exemption and a firmly held religious belief that prevents her from wearing a mask. As a result of this requirement, Kristen's 5-year-old son was forced to quit hockey because his mother was prohibited from attending unless she wore a mask. Kristen has been censored and "fact checked" on social media for reporting information that went against the false narrative causing her embarrassment.

6. Upon returning from visiting her family for Thanksgiving, Kristen was told by her employer that she had to quarantine despite not being sick and not having been exposed to anyone with any illness, in accordance with the Emergency Mandates. This mandatory quarantine of a healthy person placed a substantial burden on her well-established Constitutional

right to travel. Members of her own family have great fear caused by believing the truth of the data being presented by the Defendants and reported by mainstream news regarding the danger of COVID-19, which has caused ostracizing and separation of family members from Kristen.

7. **Dr. Douglas Frank -** Dr. Douglas Frank is a scientist, teacher, and researcher who has been working to create and develop a business related to the analysis and understanding of statistical data regarding COVID-19 and other topics of public interest. Dr. Frank has used social media and a web presence to demonstrate his work and build his business. Because the Defendants have misled the public about "case" and "death" counts related to COVID-19, a number of social media platforms and news outlets have claimed his work was illegitimate or false. This has created substantial difficulties in launching his business and obtaining customers. The public ridicule he has been the victim of has been directly attributable to the lack of integrity in the statistics promulgated by the Defendants.

8. It has also been exceedingly difficult for Dr. Frank to perform in his role educating the public. The data related to COVID-19 is frequently presented in ways that are intentionally misleading and where it is difficult or impossible to analyze in a way that is useful for the public as a tool of comparison to other diseases. This has resulted in Dr. Frank being forced to spend substantial amounts of time without pay to develop the portfolio necessary to promote his business.

B. Defendants

The Defendants in this action are:

9. The Department of Health & Human Services ("DHHS"). As used in this Complaint, the term DHHS shall mean and include the DHHS itself, and all other Defendants specifically named herein.

10. DHHS Secretary Norris Cochran (in his role as DHHS Secretary and his individual capacity).

11. Chief Information Officer for the DHHS.

12. The Centers for Disease Control and Prevention ("CDC").

13. CDC Director Rochelle Walensky (in her role as CDC Director and his individual capacity).

14. The National Center for Health Statistics ("NCHS").

15. NCHS Director Brian C. Moyer (in his role as Director and his individual capacity)

16. Office of Management and Budget Director Shalanda Young

17. John and/or Jane Doe[s] 1-20– Plaintiffs humbly request the Court to hold these unnamed individuals as open until such time as we can ensure we have properly identified all relevant personnel. Plaintiffs have made a good-faith effort to identify relevant personnel but cannot ensure all relevant personnel are included based on available public data.

Jurisdiction and Venue

18. This Court has jurisdiction over this action under 28 U.S. Code § 1331 and 28 U.S. Code § 1361. This action is also brought under the Paperwork Reduction Act ("PRA") as amended to include the Information Quality Act (also known as the Data Quality Act) ("IQA") requirement that there be "integrity, quality, and utility" in the Federal statistical system as well as the more general statements of purpose under 44 USCS § 3501. Finally, this action is also brought under the Administrative Procedures Act. DHHS failed to follow proper rulemaking procedures under the Information Quality Act, the PRA, and the APA.

19. Pursuant to 28 USCS § 1391(e), the FRCP, and local rules, venue is proper in this Court.

Facts

The PRA

20. The PRA clearly mandates that data reporting be made with due consideration paid to "… integrity, quality and utility…." It also includes the following:

> The purposes of this subchapter [44 USCS §§ 3501 et seq.] are to—
>
> **(4)** improve the quality and use of Federal information to strengthen decision making, accountability, and openness in Government and society; …
>
> **(7)** provide for the dissemination of public information on a timely basis, on equitable terms, and in a manner that promotes the utility of the information to the public and makes effective use of information technology; …
>
> **(11)** improve the responsibility and accountability of the Office of Management and Budget and all other Federal agencies to Congress and to the public for implementing the information collection review process, information resources management, and related policies and guidelines established under this subchapter.

21. Plaintiffs have found limited applicable case law addressing standing in requests for injunctive relief based on violations of the PRA. The cases we have found have been related to requests for money damages which are not being sought here or with the collection of information as opposed to collection and reporting generally. *Teledyne, Inc. v. United States*, 50 Fed. Cl. 155 (2001); *Sutton v. Providence St. Joseph Med. Ctr*., 192 F.3d 826 (1999). There are few other cases on this topic, and Plaintiffs have not seen any that were actually relevant.

22. Based on the plain language of the statute it is clear the Plaintiffs have standing to bring action when data is being collected improperly and presented inaccurately or in a manner that does not promote utility. This position is further demonstrated by the statement that a goal of the legislation is to "improve the responsibility and accountability of the Office of Management and Budget and all other federal agencies to… the public…" [emphasis added].

The IQA

23. The Information Quality Act enacted by Congress in December 2000 requires the Office of Management and Budget (OMB) to "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies"… in accordance with the purposes and provisions of …the Paperwork Reduction Act (PRA).

The Administrative Procedures Act (APA)

24. While the APA, 5 U.S.C. §701-706, does not confer subject matter jurisdiction, it does permit challenges to the actions of a federal agency like HHS and CDC. Sec. 702 gives "a person suffering legal wrong because of an agency action or (who) is adversely affected or aggrieved by agency action…" the right to judicial review of the action. This provision, enacted in 1946, was amended in 1976 to remove the defense of sovereign immunity as a bar to judicial review of Federal administrative action that is otherwise subject to judicial review. The scope of review grants broad equitable power to the reviewing Court (Sec. 706).

25. Original jurisdiction found under 28 U.S.C. §1331 authorizes federal courts to hear claim arising under the APA as well as "non-statutory" and Constitutional claims. *Trudeau v. Fed. Trade Commission,* 456 F.3d 178, 185 (D.C. Cir. 2006) An example of a "non-statutory claim" arises when, as here, Defendants have acted *ultra vires* by plainly violating an unambiguous and mandatory legal requirement of a statute. *Leedom v. Kyne, 358 U.S. 184, 188-89.*

Illegal Rulemaking Effecting Changes to Cause of Death Data Collection and Reporting

26. 18. On March 24, 2020 the CDC published guidelines[1] changing, for the first time in 17 years, the data collection and reporting methods used to determine the cause of death. This was not done as a general reform for cause of death reporting, but rather only for a single disease – COVID-19. This was also done without following the rulemaking processes or procedures required by law.

27. In altering the reporting rule for a single disease, DHHS has created a situation in which the reporting of the number of deaths attributed to COVID-19 is not comparable or consistent with reporting for any other cause of death. The prior method for determining cause of deaths in the United States is based on *2003 CDC's Medical Examiners' & Coroners' Handbook on Death Registration and Fetal Death Reporting and the CDC's Physicians' Handbook on Medical Certification of Death* (the "Handbook"). This handbook creates a universal method by which cause of death is determined in the United States. In discussing how the cause of death section is completed on a death certificate the guide states:

> The cause-of-death section consists of two parts. Part I is for reporting a chain of events leading directly to death, with the immediate cause of death (the final disease, injury, or complication directly causing death) online (a) and the underlying cause of death (the disease or injury that initiated the chain of events that led directly and inevitably to death) on the lowest used line. Part II is for reporting all other significant diseases, conditions, or injuries that contributed to death but which did not result in the underlying cause of death given in Part I. (Centers for Disease Control and Prevention, 2003).

28. The Handbook includes substantial discussion on the importance of standardization and accuracy in determining cause of death even noting that the death certificate is considered *prima*

[1] COVID-19 Alert No. 2 https://www.cdc.gov/nchs/data/nvss/coronavirus/Alert-2-New-ICD-code-introduced-for-COVID-19-deaths.pdf

facie evidence in court. It notes the importance of the death certificate in ensuring accurate statistical data and talks about the importance of that data.

29. The new rule issued on March 24, 2020 casts aside any consideration of integrity or utility in the data instead stating:

a. "… the rules for coding and selection of the underlying cause of death are expected to result in COVID-19 being the underlying cause more often than not." And

b. "COVID-19 should be reported on the death certificate for all decedents where the disease caused or is assumed to have caused or contributed to death."

30. The Handbook notes the relevance of the death certificates and related statistics to determining funding. The relationship between integrity in reporting deaths and funding demonstrates that any rule changing this formula would be substantive and need to go through the APA rulemaking process.

Use of PCR Testing and Publication of False PCR Testing Results

31. COVID-19 cases can be diagnosed through the application of certain criteria by a healthcare provider to a patient or through laboratory testing. Financial incentives to health care providers and/or hospitals provide motivation to inflate the case and death numbers.

32. Physician diagnosis of COVID-19 requires a patient meet certain epidemiological criteria and manifest certain symptoms of the disease. Diagnosing this disease by symptoms is equally unhelpful in that many symptoms of COVID-19 are identical to the flu and other common diseases with no real distinguishing differences, with the exception of possible loss of taste and/or smell. Even the loss of taste or smell are not determinative for this diagnosis as they can arise from other non-COVID causes.

33. The incredibly vague criteria for physician diagnosis of COVID-19 combined with the increased funding for COVID "cases" and "deaths" has resulted in a massive re-categorization of flu cases as COVID-19 cases. Until recently, public CDC statistics showed statistics for influenza, but those statistics have now been hidden from the public.

34. The laboratory testing for COVID-19 is also demonstrably misleading. The primary test for diagnosing an active case of COVID-19 is the PCR test. The FDA has approved PCR tests from numerous manufacturers under Emergency Use Authorization ("EUA") rules. In granting the EUAs, the FDA has set no national standards for what test results constitute a "case" of COVID-19. Further, it appears that many if not all the tests were developed without an isolated sample of the SARS-CoV-2 virus that they were supposed to be testing for. It is unclear which tests, if any, were developed using an isolated sample and what impact the lack of a sample would have on the accuracy of the tests.

35. What is not unclear is that the tests cannot, by themselves, provide any meaningful indication of whether a patient has COVID-19. This fact is made quite clear by the disclaimers found in most, if not all, of the test kits that state that the kits cannot diagnose COVID-19.

36. The reason for the disclaimer is that a PCR test can only test for fragments of a virus. Viruses are a constant reality of life and the human body deals with them through an immune response. A virus can only result in a disease if it reaches a certain "viral load" which means a substantial amount of that virus is in the infected person's body. It is thought that a PCR test may provide some indication of viral load but that is not conclusive, and the test also cannot determine whether or not the viral load is sufficient for a person to be infected or transmit infection for COVID-19 disease.

37. Further, the means by which a PCR test determines whether a viral fragment exists in a sample is by bonding that fragment with a separately introduced particle and then amplifying the new product. Each amplification is called a cycle and is exponential doubling of the previous cycle number. Scientists have shown that the lower the cycle threshold in which the bonded particle is found (i.e. a positive result), the more viral fragments would be in the patient's system. Because the PCR test can detect various types of viral fragments, even a positive test at a lower cycle does not establish the presence of SARS-CoV-2 virus, the virus that allegedly causes COVID-19 disease.

38. In issuing the EUAs for the PCR tests, the FDA failed to create a standard cycle threshold that would indicate a positive or negative COVID-19 test. Instead, each manufacturer was approved for various cycle thresholds. Most of the cycle threshold values were set very high – well above 35. According to Dr. Fauci a cycle threshold value that is greater than 35 is not meaningful.

39. The PRA and IQA make it clear that Congress intended for honesty and integrity in data reporting. The OMB backs this position in its many rules interpreting these statutes and even the NCHS itself notes the critical nature of ensuring integrity and utility in statistics. These statutes create a duty to the public as well as others, of truthful data collection and reporting concerning deaths. The public has, again, according to the plain language of the law, a strong interest and even a role in ensuring the data is based on integrity and useful.

40. DHHS has breached its duty by not following the law. As a result of DHHS's failure to follow the law, Plaintiffs have been injured. They have been injured by the policies implemented in response to this misleading data. No two better examples of abuse of discretion could be imagined than these:

c. Changing the method for accounting for death for a single disease thus rendering data about deaths for that disease useless in understanding the danger of said disease. This happened when precautions should have been taken to prevent overcounting since additional funds were offered for diagnosis/death from that disease.

d. Using a test that includes disclaimer language in its instruction manual concerning its validity for diagnosing COVID-19, and which test was created without any national standard defining a "case".

41. When Congress delegated power to these regulatory agencies to leverage their limited legislative power, it was Constitutionally required to ensure it did so with standards. In this case, Congress did set standards – "utility" and "integrity" amongst them.

42. The facts as alleged within this Complaint show that the statistics, information, data, etc. related to COVID-19 "deaths" and "cases" are being promulgated in a way that involves neither integrity nor utility. The substantive rules, rules that had a substantial legal impact – were created without following mandatory procedures and meeting mandatory standards prescribed in the PRA, IQA and APA, and the result has reaped unthinkable levels of destruction on our nation.

43. But for the violation of the integrity, utility, and other standards set out in the PRA and IQA, our nation and the Plaintiffs would not be suffering. But for the violation of the APA, PRA, and IQA, the actual numbers for cases and deaths would be accurately reported. The DHHS, through the CDC and NCHS, adopted numerous rules related to the counting of COVID-19 deaths and cases that were based on false/incorrect information and done contrary to the methods used for any other disease.

44. The false COVID-19 "case" and "death" COUNTS informed the COVID-19 response of Ohio government officials and agencies. They precipitated, shaped and were used to justify both the Emergency itself and the Emergency Mandates, which have foreseeably damaged many people throughout Ohio. Now, if the Plaintiffs do not have the right to challenge the unlawfulness of this revised rule for reporting this one type of death, plaintiffs will be left to continue to suffer for the foreseeable future. The APA, PRA, and IQA were all put in place as checks on the already overly broad powers on regulatory agencies – the people do and must have a right to enforce those protections.

COUNT I – DECLARATORY JUDGMENT: DHHS violated the PRA, IQA, and APA by issuing the March 24, 2020 rule changing the death reporting procedures as they apply to COVID-19.

45. The foregoing paragraphs are hereby incorporated as if fully set forth herein.

46. The process by which the unique substantive rule for reporting COVID-19 related deaths was established violated the PRA, IQA, and APA. The PRA and IQA require that statistical data have "utility" and "integrity." This COVID-19 death reporting rule violated both standards. Further, the rule was substantive and could only be adopted and implemented through a proper rulemaking process under the APA, and that process was not followed.

47. Those improperly passed rules have created chaos throughout the nation, cost untold trillions of dollars, and have informed and been used to justify the Emergency Mandates that have harmed the Plaintiffs. A ruling by the Court that ordered that the issuance of this rule was illegal and that death reporting should be carried out as it has been with every other disease since 2003 would begin to allow the political process to repair the damage that has occurred. As such,

we humbly request that the Court grant the injunction against the implementation of this illegal rule.

COUNT II – DECLARATORY JUDGMENT: DHHS is reporting "Case" and "Death" data it knows to be misleading in violation of the PRA, IQA, and the implied Constitutional / Statutory Duty of Honesty and Fair Dealing

48. The foregoing paragraphs are hereby incorporated as if fully set forth herein.

49. DHHS has violated an implied Constitutional / Statutory duty of honesty and fair dealing. The implied duty arises because:

a. Unelected bureaucrats are not accountable to the public through elections and cannot even be fired easily due to a recognized legal interest in their positions. An implied right of action must exist for the public where said bureaucrats are not performing their jobs with honesty and fair dealing. To hold otherwise would be to invalidate our most fundamental rules of accountability within government.

b. Separation of powers has been dramatically diminished over the years and without an enforceable, implied duty of honesty and fair dealing, there would exist unconstitutionally overbroad powers consolidated into what would essentially be a fourth quasi-branch of government.

c. Legal and evidentiary rules as well as numerous cases have relied on the truthfulness of executive-branch agencies. This implies a duty of honesty and fair dealing must exist within those agencies.

50. The reporting of data that is known to be misleading by a regulatory agency charged with ensuring statistics are gathered and disseminated with "integrity" and in a "useful" manner is facially illegal. The data is used to set policy and has been presented as evidence in a court of

law, with profound implications for private citizens and businesses, including innumerable, unprecedented, prolonged invasions of their Constitutional rights. While an elected politician may be protected from lying under the speech and debate clause, this protection does not apply to unelected bureaucrats.

COUNT III –INJUNCTIVE RELIEF: Enjoining DHHS from further "Case" reporting based on PCR testing and other misleading criteria that violate the PRA and IQA's "utility" and "integrity" clause.

51. The foregoing paragraphs are hereby incorporated as if fully set forth herein

52. Dr. Fauci has stated that PCR tests run over 35 cycles are meaningless. The manuals for PCR tests have noted the tests should not be used to diagnose COVID-19. The use of PCR testing, particularly as currently approved by the FDA, is a violation of the "utility" and "integrity" requirements of the PRA and IQA.

53. Plaintiffs request the Court enjoin further "case" reporting based on PCR testing given that it is not reliable and thus cannot be reported with integrity or in a way that is useful which is in clear violation of the PRA and IRQ, and at the same time is injuring Plaintiffs and infringing their constitutional rights.

COUNT IV –INJUNCTIVE RELIEF: Enjoining DHHS from further "Death" reporting based on the March 24, 2020 rule changing the death reporting procedures for COVID-19.

54. The foregoing paragraphs are hereby incorporated as if fully set forth herein

55. Plaintiffs request the Court enjoin further "death" reporting based on the March 24 ,2020 rule change given that the rulemaking violated the APA, the rule results in COVID-19 death

reporting that is not reliable and violates the standards of "integrity" and "utility" required by the PRA and IRQ, and the rule is injuring Plaintiffs and infringing their constitutional rights.

COUNT V – MANDAMUS

56. The foregoing paragraphs are hereby incorporated as if fully set forth herein.

57. Plaintiffs request that the Court grant a writ of mandamus to compel the appropriate Defendants and to follow the law and/or order their staff to do the same.

Prayers for Relief

58. State and federal action across the country is being predicated on data that is both incorrect and was promulgated and presented in an illegal manner and, as such, we are requesting injunctive and declaratory relief. Specifically, we humbly request that the Court issue the following relief on an emergency and then permanent basis:

    1. Enjoin the current and future use of the March 24, 2020 rule changing the death reporting procedures as they apply to COVID-19.
    2. Enjoin the current and future reporting using said COVID-19 "death" reporting rule unless and until it is properly implemented under relevant law.
    3. Enjoin the use of "case" reporting using unreliable testing procedures such as PCR testing without the proper creation of a national standard for PCR tests and a uniform definition of what a "case" is.
    4. Grant an affirmative injunction that the CDC report the accurate death data using the traditional reporting methods within 2 weeks from the grant of this injunction.

5. Grant injunctive relief against DHHS personnel violating the implied Constitutional and Statutory Duty of Honesty and Fair Dealing by misleading the public about the death and case data related to COVID-19
6. Grant a writ of mandamus and compel relevant DHHS and OMB personnel to comply with and enforce the PRA and IQA.

Respectfully submitted,

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